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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/937,221 | 07/18/2002 | Kunihiko Iizuka | 2001-1460A | 6705 |

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

DENTZ, BERNARD I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1625

DATE MAILED: 06/09/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/937,221

Applicant(s)

IIZUKA ET AL.

Examiner

Bernard Dentz

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claims 1, 6, 11 and 16 are improper unsupported claims which recite that any compound which affects the Rho receptor, both known and unknown at the filing date, will be useful for treatment of interstitial pneumonia and come under applicants control if issued as a patent.

Thus these claims are considered drawn to a separate invention, albeit improper. *and R_c. Thus the 3 values of R_a*
The generic claim is huge in the definition of R_a are 1 of the indicators for separate inventions. R_c is considered to have 4. The first 2 are monocyclic containing 1 N and monocyclic containing more than 1 N respectively. The third and fourth are polycyclic containing 1N and polycyclic containing more than 1N respectively.

Thus restriction is required as follows:

- I. Claims 1, 6, 11 and 16 drawn to use of any compound which affects the Rho receptor to treat interstitial pneumonia or pulmonary fibrosis.
- II. Claims 2-5, 7-10, 12-15 and 17-21 drawn to compounds and associated subject matter wherein R_a contains a 1, 4-substituted cyclohexane group and R_c is 1N monocyclic.
- III. Claims 2-4, 7-9, 12-14 and 17-19 and 21 drawn to compounds and associated subject matter wherein R_a contains an at least disubstituted benzene ring where the relative positions of the 2 main substituents *are* not fixed as in the above cyclohexano *they are* containing group and R_c is 1N monocyclic.
- IV. Claims 2, 7, 12, 17 and 21 drawn to compounds and associated subject matter wherein R_a contains a piperidine or 3, 4-dehydropiperidine group and R_c is 1N monocyclic.

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- V. Claims 2, 3, 7, 8, 12, 13, 17, 18 and 21 where R_a is value a and R_c is 1N polycyclic.
- VI. Claims 2, 3, 7, 8, 12, 13, 17, 18 and 21 wherein R_b is value b and R_c is 1N polycyclic.
- VII. Claims 2, 7, 12, 17 and 21 wherein R_b is value C and R_c is 1N polycyclic.
- VIII. Claims 2, 3, 7, 8, 12, 13, 17, 18 and 21 where R_a is value a and R_c is poly N monocyclic.
- IX. Claims 2, 3, 7, 8, 12, 13, 17, 18 and 21 wherein R_a is value b and R_c is poly N monocyclic.
- X. Claims 2, 7, 12, 17 and 21 where R_b is value C and R_c is poly N monocyclic.
- XI. Claims 2-4, 7-9, 12-14, 17-19 and 21 where R_b is value a and R_c is poly N polycyclic.
- XII. Claims 2, 3, 7, 8, 12, 13, 17, 18 and 21 where R_b is value b and R_c is poly N polycyclic.
- XIII. Claims 2, 7, 12, 17 and 21 where R_b is value C and R_c is poly N polycyclic.

Although the classification have not been specifically set out it can be appreciated from the list of values for "Optionally substituted heterocyclic containing nitrogen" for R_c set out on pages 22 and 23 that there are many all over classes 544, 546 and 548.

Thus restriction for effective examination purposes is proper in view of the directly above and earlier comments on the diversity and breadth of the subject matter.

In case no generic claims are later found allowable applicants must now elect a single disclosed species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is (703) 308-4544. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703) 308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 3084556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Dentz/LR
June 5, 2003



BERNARD DENTZ
PRIMARY EXAMINER
GROUP 1600